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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/296,031 04/21/99 LYONS PH.D.

S D6218

EXAMINER

009629 HM12/0706

MORGAN, LEWIS & BOCKIUS

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WASHINGTON DC 20036-5869

CHEN, S	
ART UNIT	PAPER NUMBER

1633

DATE MAILED:

07/06/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

09/296,031

Applicant(s)

Lyons et al.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 13, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: The change of the term "level" to "presence" of chlorotoxin binding in claim 15 raises new 35 U.S.C. 112 first paragraph rejection.

4. ☒ Applicant's reply has overcome the following rejection(s):
35 U.S.C. 112 second paragraph rejection when the amendment is entered.
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
Applicants argue that the Official action mailed 3-13-01 (Paper No. 8) offers "no evidence in the form of references and does not specifically identify what information is missing and why one skilled in the art could not supply the information"
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: None
Claim(s) objected to: None
Claim(s) rejected: 15-31
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

Deborah J. R. Clark
DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

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DETAILED ACTION

Continued from Advisory Action:

without undue experimentation” (amendment page 4). This is not found persuasive because of reasons of record and that it was known in the art that the malignancy and physiology of the two types of melanoma cells, non-metastasis and metastasis, could vary dramatically from each other, and it is unclear what type of chlorotoxin binding pattern would be for various types of melanoma cells. No prior art has taught whether and how chlorotoxin would bind to various types of melanoma cells. Further, the control tissue sample shows background staining with chlorotoxin as shown in Figure 8, it is unclear how to distinguish a control tissue sample, such as a normal breast skin, with melanoma cells since the amended claim reads on the presence of binding is indicative of the presence of the cancer. Thus it would require one skilled in the art at the time of the invention undue experimentation to practice over the full scope of the claimed invention.

Applicants argue that “the control samples in the specification contain no chlorotoxin and any signal is therefore due to the particular detection method employed... and it would be routine to distinguish background staining due to a particular detection method from specific binding of chlorotoxin” (amendment, page 4). This is not found persuasive because of the reasons set forth above and the reasons of record, and further that the claimed method is based on the binding of added chlorotoxin to the antigen present on the targeted tissue sample cells. There could be more

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than one type of antigens that could bind to chlorotoxin and the absence of one type of antigen on control sample cells does not mean said sample cells would lack the binding of chlorotoxin. Thus, claims 15-31 remain rejected under 35 U.S.C 112 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.